

In re Application of Van Urk *et al.*  
Application No. 09/890,297  
Art Unit No. 1637

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**Amendments to the Claims**

Claims 1-53 (canceled)

Claim 54 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to cation exchange chromatography in the negative mode with respect to the albumin in order to yield an albumin-containing cation exchange product;
- (2) subjecting the albumin-containing cation exchange product, with or without intervening purification steps, to anion exchange chromatography to yield an albumin-containing anion exchange product; and
- (3) placing the albumin-containing anion exchange product, without further purification, into a final container for therapeutic use;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (1) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 55 (previously presented): A process according to Claim 54 wherein the albumin solution subjected to cation exchange chromatography in step (1) of claim 54 contains glycosylated albumin and the glycosylated albumin is bound during the said cation exchange step.

Claim 56 (previously presented): A process according to Claim 54 wherein the cation exchange step utilises a matrix which comprises immobilised sulfopropyl substituents as cation exchangers.

Claim 57 (canceled)

Claim 58 (canceled)

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Claim 59 (previously presented): A process according to Claim 54 wherein the albumin solution subjected to cation exchange chromatography in step (1) of claim 54 has an octanoate ion concentration of 2-15mM.

Claim 60 (previously presented): A process according to Claim 54 wherein the albumin solution subjected to cation exchange chromatography in step (1) of claim 54 has an octanoate ion concentration of 5-10mM.

Claim 61 (previously presented): A process according to Claim 54 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

Claim 62 (previously presented): A process according to Claim 61 wherein prior to the cation exchange step the albumin solution undergoes conditioning by addition of an octanoate salt.

Claim 63 (previously presented): A process according to Claim 54 wherein the anion exchange step utilises a matrix which comprises immobilised dialkylaminoalkyl substituents as anion exchangers.

Claim 64 (previously presented): A process according to Claim 54 wherein the anion exchange step is run in the negative mode with respect to the albumin.

Claim 65 (previously presented): A process according to Claim 64 wherein the albumin solution which undergoes anion exchange chromatography has a pH of 4.0-5.2.

Claim 66 (previously presented): A process according to Claim 64 wherein the albumin solution which undergoes anion exchange chromatography has a conductivity of less than 4.0mS.cm<sup>-1</sup>.

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Claim 67 (previously presented): A process according to Claim 54 wherein the anion exchange step is run in positive mode with respect to the albumin.

Claim 68 (previously presented): A process according to Claim 67 wherein the albumin solution which undergoes positive mode anion exchange chromatography has a pH of 6.0-8.0.

Claim 69 (previously presented): A process according to Claim 67 wherein the concentration of the albumin in the albumin solution which undergoes positive mode anion exchange chromatography is 10-100g.L<sup>-1</sup>

Claim 70 (previously presented): A process according to Claim 67 wherein the albumin solution which undergoes positive mode anion exchange chromatography has a conductivity of 1.0-1.5mS.cm<sup>-1</sup>.

Claim 71 (previously presented): A process according to Claim 67 wherein the albumin is eluted in the anion exchange step using a buffer comprising a compound having a specific affinity for albumin.

Claim 72 (previously presented): A process according to Claim 71 wherein the buffer comprises 20-90mM phosphoric acid salt.

Claim 73 (previously presented): A process according to Claim 67 wherein the albumin is eluted in the anion exchange step with a buffer of pH6.0-8.0.

Claim 74 (previously presented): A process according to Claim 54 wherein, prior to the anion exchange step, the albumin solution undergoes at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 75 (previously presented): A process according to Claim 54 wherein the process is preceded by at least one step selected from the group consisting of: fermentation; primary separation; concentration; conditioning; cation exchange chromatography; anion exchange chromatography; and affinity chromatography.

Claim 76 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to cation exchange chromatography in the negative mode with respect to the albumin in order to yield an albumin-containing cation exchange product;
- (2) subjecting the albumin-containing cation exchange product, with or without intervening purification steps, to anion exchange chromatography to yield an albumin-containing anion exchange product; and
- (3) placing the albumin-containing anion exchange product, without further purification, into a final container for therapeutic use,

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin-containing anion exchange product is subjected to at least one step selected from the group consisting of buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; heating; cooling; and conditioning, before being placed into the said final container; and wherein the albumin solution subjected to cation exchange chromatography in step (1) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 77 (previously presented): A process according to Claim 76 wherein the albumin solution subjected to cation exchange chromatography in step (1) of claim 76 contains glycosylated albumin and the glycosylated albumin is bound during the said cation exchange step.

Claim 78 (previously presented): A process according to Claim 76 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH-adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

Claim 79 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and
- (3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use,

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin-containing cation exchange product is subjected to at least one step selected from the group consisting of buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; heating; cooling; and conditioning, before being placed into the said final container; and wherein the albumin solution subjected to cation exchange chromatography in step (2) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 80 (previously presented): A process according to Claim 79 wherein the albumin solution subjected to cation exchange chromatography in step (2) of claim 79 contains glycosylated albumin and the glycosylated albumin is bound during the said cation exchange step.

Claim 81 (previously presented): A process according to Claim 79 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH-adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

Claim 82 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i) subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
- (ii) collecting an albumin-containing cation exchange eluate;
- (iii) subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv) collecting an albumin-containing anion exchange eluate;
- (v) subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi) collecting an albumin-containing affinity chromatography eluate;
- (vii) subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
- (viii) collecting the albumin-containing affinity chromatography flow through;
- (ix) subjecting the affinity chromatography flow through to a cation exchange chromatography step run in negative mode with respect to the albumin;
- (x) collecting the albumin-containing cation exchange flow through;
- (xi) subjecting the cation exchange flow through to an anion exchange chromatography step run in negative mode; and
- (xii) collecting the albumin-containing anion exchange flow through from step (xi);  
thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (ix) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 83 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i). subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
- (ii). collecting an albumin-containing cation exchange eluate;
- (iii). subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv). collecting an albumin-containing anion exchange eluate;
- (v). subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi). collecting an albumin-containing affinity chromatography eluate;
- (vii). subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
- (viii). collecting the albumin-containing affinity chromatography flow through;
- (ix). subjecting the affinity chromatography flow through to a cation exchange chromatography step run in negative mode with respect to the albumin;
- (x). collecting the albumin-containing cation exchange flow through;
- (xi). subjecting the cation exchange flow through to an anion exchange chromatography step run in positive mode; and
- (xii). eluting from the anion exchange matrix an anion exchange eluate,  
thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (ix) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 84 (previously presented): A process according to Claim 82 wherein any of the said purification steps are optionally preceded or followed by at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 85 (previously presented): A process according to Claim 83 wherein any of the said purification steps are optionally preceded or followed by at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 86 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i) subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
- (ii) collecting an albumin-containing cation exchange eluate;
- (iii) subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv) collecting an albumin-containing anion exchange eluate;
- (v) subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi) collecting an albumin-containing affinity chromatography eluate;
- (vii) subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
- (viii) collecting the albumin-containing affinity chromatography flow through;
- (ix) subjecting the affinity matrix flow through to an anion exchange chromatography step run in negative mode with respect to the albumin;
- (x) collecting the albumin-containing anion exchange flow through from step (ix);



- (xi) subjecting the albumin-containing anion exchange flow through solution  
~~purified by the anion exchange chromatography step~~ to a cation exchange  
chromatography step run in negative mode with respect to the albumin; and
- (xii) collecting the albumin-containing cation exchange flow through,  
thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin  
solution subjected to cation exchange chromatography in step (xi) has an albumin  
concentration of 10-250g.L<sup>-1</sup>.

Claim 87 (currently amended): A process for purifying an albumin solution, the process  
comprising the steps of:

- (i). subjecting an albumin solution to a cation exchange chromatography step run  
in positive mode with respect to the albumin;
- (ii). collecting an albumin-containing cation exchange eluate;
- (iii). subjecting the cation exchange eluate to an anion exchange chromatography  
step run in positive mode with respect to the albumin;
- (iv). collecting an albumin-containing anion exchange eluate;
- (v). subjecting the anion exchange eluate to an affinity chromatography step run in  
positive mode with respect to the albumin;
- (vi). collecting an albumin-containing affinity chromatography eluate;
- (vii). subjecting the affinity chromatography eluate to an affinity chromatography  
step run in negative mode with respect to the albumin and in positive mode  
with respect to glycoconjugates;
- (viii). collecting the albumin-containing affinity chromatography flow through;
- (ix). subjecting the affinity matrix flow through to an anion exchange  
chromatography step run in positive mode with respect to the albumin;
- (x). eluting from the anion exchange matrix an anion exchange eluate;
- (xi). subjecting the albumin-containing anion exchange eluate solution~~purified by  
the anion exchange chromatography step~~ to a cation exchange  
chromatography step run in negative mode with respect to the albumin; and

- (xii). collecting the albumin-containing cation exchange flow through, thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (xi) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 88 (previously presented): A process according to Claim 86 wherein any of the said purification steps are optionally preceded or followed by at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; addition of reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 89 (previously presented): A process according to Claim 87 wherein any of the said purification steps are optionally preceded or followed by at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; addition of reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 90 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and
- (3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use,

thereby providing a purified albumin solution; wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (2) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 91 (previously presented): A process according to Claim 90 wherein the albumin solution subjected to cation exchange chromatography in step (2) of claim 90 contains glycosylated albumin and the glycosylated albumin is bound during the said cation exchange step

Claim 92 (previously presented): A process according to Claim 90 wherein the cation exchange step utilises a matrix which comprises immobilised sulfopropyl substituents as cation exchangers.

Claim 93 (canceled)

Claim 94 (canceled)

Claim 95 (previously presented): A process according to Claim 90 wherein the albumin solution that undergoes cation exchange chromatography has an octanoate ion concentration of 2-15mM.

Claim 96 (previously presented): A process according to Claim 90 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

Claim 97 (previously presented): A process according to Claim 96 wherein prior to the cation exchange step the albumin solution undergoes conditioning by addition of an octanoate salt.

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Claim 98 (previously presented): A process according to Claim 90 wherein the anion exchange step utilises a matrix which comprises immobilised dialkylaminoalkyl substituents as anion exchangers.

Claim 99 (previously presented): A process according to Claim 90 wherein the anion exchange step is run in the negative mode with respect to the albumin.

Claim 100 (previously presented): A process according to Claim 99 wherein the albumin solution which undergoes anion exchange chromatography has a pH of 4.0-5.2.

Claim 101 (previously presented): A process according to Claim 99 wherein the albumin solution which undergoes anion exchange chromatography has a conductivity of less than  $4.0\text{mS.cm}^{-1}$ .

Claim 102 (previously presented): A process according to Claim 90 wherein the anion exchange step is run in positive mode with respect to the albumin.

Claim 103 (previously presented): A process according to Claim 102 wherein the albumin solution which undergoes positive mode anion exchange chromatography has a pH of 6.0-8.0.

Claim 104 (previously presented): A process according to Claim 102 wherein the concentration of the albumin in the albumin solution which undergoes positive mode anion exchange chromatography is  $10\text{-}100\text{g.L}^{-1}$

Claim 105 (previously presented): A process according to Claim 102 wherein the albumin solution which undergoes positive mode anion exchange chromatography has a conductivity of  $1.0\text{-}1.5\text{mS.cm}^{-1}$ .

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Claim 106 (previously presented): A process according to Claim 102 wherein the albumin is eluted in the anion exchange step using a buffer comprising a compound having a specific affinity for albumin.

Claim 107 (previously presented): A process according to Claim 106 wherein the buffer comprises 20-90mM phosphoric acid salt.

Claim 108 (previously presented): A process according to Claim 102 wherein the albumin is eluted in the anion exchange step with a buffer of pH6.0-8.0.

Claim 109 (previously presented): A process according to Claim 90 wherein, prior to the cation exchange step, the albumin solution undergoes at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning.

Claim 110 (previously presented): A process according to Claim 90 wherein the process is preceded by at least one step selected from the group consisting of: fermentation; primary separation; centrate conditioning; cation exchange chromatography; anion exchange; and affinity chromatography.

Claim 111 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and

(3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use,  
wherein the albumin solution is a recombinant albumin solution, and wherein, prior to the cation exchange step, the albumin solution undergoes at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning; and wherein the albumin solution subjected to cation exchange chromatography in step (2) has an albumin concentration of 10-250g.L<sup>-1</sup>.

Claim 112 (previously presented): A process according to Claim 111 wherein the albumin solution subjected to cation exchange chromatography in step (2) of claim 111 contains glycosylated albumin and the glycosylated albumin is bound during the said cation exchange step.

Claim 113 (previously presented): A process according to Claim 111 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH-adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

Claim 114 (previously presented): A process according to Claim 54 wherein the albumin solution that undergoes cation exchange chromatography has a pH of 4.5-6.0.

Claim 115 (previously presented): A process according to Claim 90 wherein the albumin solution that undergoes cation exchange chromatography has a pH of 4.5-6.0.

Claim 116 (currently amended): A process according to Claim 54, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of 20-~~70~~250g.L<sup>-1</sup>.

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Claim 117 (previously presented): A process according to Claim 54, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

Claim 118 (currently amended): A process according to Claim 76, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}70\text{ }250 \text{ g.L}^{-1}$ .

Claim 119 (previously presented): A process according to Claim 76, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

Claim 120 (currently amended): A process according to Claim 79, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}70\text{ }250 \text{ g.L}^{-1}$ .

Claim 121 (previously presented): A process according to Claim 79, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

Claim 122 (currently amended): A process according to Claim 82, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}70\text{ }250 \text{ g.L}^{-1}$ .

Claim 123 (previously presented): A process according to Claim 82, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

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Claim 124 (currently amended): A process according to Claim 83, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}\cancel{70}\underline{250}\text{g.L}^{-1}$ .

Claim 125 (previously presented): A process according to Claim 83, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50\pm 10\text{g.L}^{-1}$ .

Claim 126 (currently amended): A process according to Claim 86, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}\cancel{70}\underline{250}\text{g.L}^{-1}$ .

Claim 127 (previously presented): A process according to Claim 86, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50\pm 10\text{g.L}^{-1}$ .

Claim 128 (currently amended): A process according to Claim 87, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}\cancel{70}\underline{250}\text{g.L}^{-1}$ .

Claim 129 (previously presented): A process according to Claim 87, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50\pm 10\text{g.L}^{-1}$ .

Claim 130 (currently amended): A process according to Claim 90, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}\cancel{70}\underline{250}\text{g.L}^{-1}$ .



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Claim 131 (previously presented): A process according to Claim 90, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

Claim 132 (currently amended): A process according to Claim 111, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $20\text{--}70$ ~~250~~ $\text{ g.L}^{-1}$ .

Claim 133 (previously presented): A process according to Claim 111, wherein the albumin solution subjected to the negative mode cation exchange chromatography step has an albumin concentration of  $50 \pm 10 \text{ g.L}^{-1}$ .

Claim 134 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to cation exchange chromatography in the negative mode with respect to the albumin in order to yield an albumin-containing cation exchange product;
- (2) subjecting the albumin-containing cation exchange product, with or without intervening purification steps, to anion exchange chromatography to yield an albumin-containing anion exchange product; and
- (3) placing the albumin-containing anion exchange product, without further purification, into a final container for therapeutic use;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (1) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 135 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to cation exchange chromatography in the negative mode with respect to the albumin in order to yield an albumin-containing cation exchange product;
- (2) subjecting the albumin-containing cation exchange product, with or without intervening purification steps, to anion exchange chromatography to yield an albumin-containing anion exchange product; and
- (3) placing the albumin-containing anion exchange product, without further purification, into a final container for therapeutic use,

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin-containing anion exchange product is subjected to at least one step selected from the group consisting of buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; heating; cooling; and conditioning, before being placed into the said final container; and wherein the albumin solution subjected to cation exchange chromatography in step (1) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 136 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and
- (3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use,

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin-containing cation exchange product is subjected to at least one step selected from the group consisting of buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; heating; cooling; and conditioning, before being placed into the said final container; and wherein the albumin solution subjected to cation exchange chromatography in step (2) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 137 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i) subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
- (ii) collecting an albumin-containing cation exchange eluate;
- (iii) subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv) collecting an albumin-containing anion exchange eluate;
- (v) subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi) collecting an albumin-containing affinity chromatography eluate;
- (vii) subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
- (viii) collecting the albumin-containing affinity chromatography flow through;
- (ix) subjecting the affinity chromatography flow through to a cation exchange chromatography step run in negative mode with respect to the albumin;
- (x) collecting the albumin-containing cation exchange flow through;
- (xi) subjecting the cation exchange flow through to an anion exchange chromatography step run in negative mode; and
- (xii) collecting the albumin-containing anion exchange flow through from step (xi); thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (ix) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 138 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i). subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
- (ii). collecting an albumin-containing cation exchange eluate;
- (iii). subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv). collecting an albumin-containing anion exchange eluate;
- (v). subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi). collecting an albumin-containing affinity chromatography eluate;
- (vii). subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
- (viii). collecting the albumin-containing affinity chromatography flow through;
- (ix). subjecting the affinity chromatography flow through to a cation exchange chromatography step run in negative mode with respect to the albumin;
- (x). collecting the albumin-containing cation exchange flow through;
- (xi). subjecting the cation exchange flow through to an anion exchange chromatography step run in positive mode; and
- (xii). eluting from the anion exchange matrix an anion exchange eluate, thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (ix) contains enzymatically

glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 139 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i) subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
  - (ii) collecting an albumin-containing cation exchange eluate;
  - (iii) subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
  - (iv) collecting an albumin-containing anion exchange eluate;
  - (v) subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
  - (vi) collecting an albumin-containing affinity chromatography eluate;
  - (vii) subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
  - (viii) collecting the albumin-containing affinity chromatography flow through;
  - (ix) subjecting the affinity matrix flow through to an anion exchange chromatography step run in negative mode with respect to the albumin;
  - (x) collecting the albumin-containing anion exchange flow through from step (ix);
  - (xi) subjecting the albumin-containing anion exchange flow through solution ~~purified by the anion exchange chromatography step~~ to a cation exchange chromatography step run in negative mode with respect to the albumin; and
  - (xii) collecting the albumin-containing cation exchange flow through,
- thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (xi) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 140 (currently amended): A process for purifying an albumin solution, the process comprising the steps of:

- (i). subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;
  - (ii). collecting an albumin-containing cation exchange eluate;
  - (iii). subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
  - (iv). collecting an albumin-containing anion exchange eluate;
  - (v). subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
  - (vi). collecting an albumin-containing affinity chromatography eluate;
  - (vii). subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates;
  - (viii). collecting the albumin-containing affinity chromatography flow through;
  - (ix). subjecting the affinity matrix flow through to an anion exchange chromatography step run in positive mode with respect to the albumin;
  - (x). eluting from the anion exchange matrix an anion exchange eluate;
  - (xi). ~~subjecting the albumin-containing anion exchange eluate solution purified by the anion exchange chromatography step to a cation exchange chromatography step run in negative mode with respect to the albumin; and~~
  - (xii). collecting the albumin-containing cation exchange flow through,
- thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (xi) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 141 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and
- (3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use, thereby providing a purified albumin solution;

wherein the albumin solution is a recombinant albumin solution, and wherein the albumin solution subjected to cation exchange chromatography in step (2) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 142 (currently amended): A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to anion exchange chromatography in order to yield an albumin-containing anion exchange product;
- (2) subjecting the albumin-containing anion exchange product, with or without intervening purification steps, to cation exchange chromatography run in the negative mode with respect to the albumin to yield an albumin-containing cation exchange product; and
- (3) placing the albumin-containing cation exchange product, without further purification, into a final container for therapeutic use,

wherein the albumin solution is a recombinant albumin solution, and wherein, prior to the cation exchange step, the albumin solution undergoes at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and

conditioning; and wherein the albumin solution subjected to cation exchange chromatography in step (2) contains enzymatically glycosylated albumin and the enzymatically glycosylated albumin is bound during the said cation exchange step.

Claim 143 (new): A process according to Claim 116 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 144 (new): A process according to Claim 118 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 145 (new): A process according to Claim 120 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 146 (new): A process according to Claim 122 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 147 (new): A process according to Claim 124 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 148 (new): A process according to Claim 126 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.



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Claim 149 (new): A process according to Claim 128 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 150 (new): A process according to Claim 130 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.

Claim 151 (new): A process according to Claim 132 wherein prior to the negative cation exchange step the albumin solution undergoes a concentration step to achieve an albumin concentration of 20-250g.L<sup>-1</sup>.